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Review Paper

Review Article on Pharmacovigilance

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ABSTRACT

Pharmacovigilance is a scientific and regulatory field that focuses on identifying, evaluating, analyzing, and preventing adverse drug reactions and other medical problems. Its importance became evident after major drug safety tragedies particularly the thalidomide disaster which highlighted the limitations of pre-marketing clinical trials in identifying all potential risks. Over time pharmacovigilance has evolved into a structured global system supported by international organizations, regulatory frameworks, and collaborative monitoring programs. Initiatives such as the WHO Programme for International Drug Monitoring and the Pharmacovigilance Programme of India (PvPI) play a vital role in collecting and analyzing safety data to protect public health. Advances in digital technologies, real-world data, and global data-sharing platforms are further strengthening pharmacovigilance practices. Despite progress, challenges such as underreporting and limited awareness remain. Continuous international cooperation and lifecycle safety monitoring are essential to ensure the safe and effective use of medicines worldwide

INTRODUCTION

The term Pharmacovigilance is derived from the geek word pharmakon which means “drug” and the latin word Vigilare, which means ”to keep watch”.

Pharmacovigilance refers to the science and practice which involved in identifying, evaluating, comprehending and preventing side effects or any other drug related issues. In order to ensure the safe efficient use of medications everywhere, pharmacovigilance has grown to be a crucial part of contemporary medical science (1).In December 1961 the concept of pharmacovigilance came into light with the publication of case report in the renowned newspaper namely Lancet. Pharmacovigilance was officially introduced by Australian doctor W. Mc Bride. He was the first

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Australian doctor who define natural connection between serious fetal deformities and thalidomide a drug used during pregnancy (2).

According to WHO Pharmacovigilance is define as the mitigation and prevention of both acute and chronic unwanted effects of medicinal substance (3). It is essential for tracking unwanted medication reactions, spotting drug-drug interactions, spotting drug resistance, and protecting the general public's health (4). Pharmacovigilance is a key component of clinical research by identifying adverse events and medication efficacy during drug development, it ensures patient safety (5).Pharmacovigilance primarily focuses on detecting harmful and unexpected side effects that may occur even when medicines are used at recommended doses for prevention, diagnosis, or treatment (6). Effective pharmacovigilance requires close collaboration among multiple stakeholders, including regulatory authorities, pharmaceutical industries, hospitals, healthcare professionals, academic institutions, poison information centers, patients, and the media. Such coordinated efforts ensure continuous monitoring and timely reporting of adverse events (7,8,9).

The need for pharmacovigilance became clear after serious tragedies like the thalidomide disaster, which showed that testing medicines before they are approved is not enough to identify all possible risks and side effects(10,11,12). Pharmacovigilance in clinical trials is the fundamental safety framework of drug development not just a supplementary procedure activity. It ensures rapid signal detection thorough benefit-risk analysis in accordance with accepted ethical and regulatory standards and systematic and continuous monitoring of adverse events. Further, it produces the crucial safety evidence that links controlled clinical research to actual clinical practice (13,14,15).

Pharmacovigilance has become an essential part of contemporary healthcare to ensure the safe and efficient use of medications during every phase of their daily lives. Despite proving initial safety and effectiveness, pre-marketing clinical trials are constrained by small sample sizes, restricted demographics, and controlled environments. Thus continuous monitoring in practical environments is necessary to identify uncommon, postponed, or population-specific adverse effects. In this introduction the significance of pharmacovigilance as a scientific and regulatory framework that protects public health, facilitates educated benefit-risk assessment, and enhances patient safety globally is emphasized.

History

19th – early 20th century

In the late 19th century people began to take the negative effects of medications very seriously. Louis Lewin wrote a book about the negative effects of medicines in 1881 . One of the earliest approaches to medication safety monitoring is this book (16).

In the USA people became angry because many medicines were fake, unsafe or wrongly labeled. In 1905, a writer named Samuel Hopkins Adams exposed these problems in his article series called" The Great American Fraud". Because of this the government passed the pure food and drugs act in 1906 . This law later helped in the creation of the FDA and modern drug safety rules (16).

Pre Thalidomide Tragedies

In 1937 , A serious drug tragedy case happens in the USA which shaken the soul of modern drug safety system of the USA. In which a medicine called elixir sulfanilamide was made using a poisonous chemical (diethylene glycol). More than 100 people died because of it. This disaster led to much stricter rules to check drug safety before medicine could be sold. It is often called the

first major " Wake- up Call" for modern drug safety systems (16).

In the 1950s the US FDA and researchers started closely monitoring drug safety after cause of serious blood diseases like aplastic anemia were linked to an antibiotic called chloramphenicol. These safety efforts later became official law through the Kefawer-Harris amendments of 1962 , which required proper testing of drugs and reporting of harmful side effects (17).

Thalidomide and the birth of modern Pharmacovigilance

In the late 1950s and early 1960s, the use of thalidomide during pregnancy caused thousands of babies worldwide to be born with severe birth defects, including phocomelia. This tragedy is widely recognized as the key event that led to the development of modern drug safety system (10,16,18).

In response, the Sixteenth World Health Assembly in 1963 passed Resolution WHA 16.36, which called for rapid international sharing of information on adverse drug reactions. This led to the launch of a WHO pilot project for international drug monitoring in 1968 (19).

Over time, this initiative developed into the WHO Programme for International Drug Monitoring, coordinated by the Uppsala Monitoring Centre (UMC). Today, it includes more than 130 member countries and forms the foundation of the global adverse drug reaction reporting system known as VigiBase (16,19).

Consolidation into regulatory science (1990s-2000s)

Over the years, pharmacovigilance (PV) has grown from just collecting voluntary reports of side effects into a well-organized scientific and regulatory system. Today, it includes clear procedures such as managing safety cases, identifying new risks (signal detection), and carefully weighing the benefits and risks of medicines (20,21).

International organizations like the World Health Organization (WHO), the Council for International Organizations of Medical Sciences (CIOMS), and the International Council for Harmonisation (ICH) have developed common guidelines to make pharmacovigilance practices consistent across different countries (16,20,21).

In Europe, Good Pharmacovigilance Practices (GVP) and the stronger role of the European Medicines Agency (EMA) have made drug safety monitoring an important part of every stage of a medicine's life, from development to post-marketing use (16,21).

Digital, Global and Future Pharmacovigilance (2000s-Present)

Modern pharmacovigilance (PV) is no longer limited to tracking traditional side effects of medicines. It now also looks at problems such as medication errors, product quality defects, counterfeit or fake medicines, and cases where medicines do not work as expected. It also values feedback directly from patients about their experiences and treatment outcomes (16,20).

Today, pharmacovigilance uses advanced tools and technology like electronic health records, big data analysis, artificial intelligence, data mining, social media, and mobile apps. These tools help detect safety issues faster and allow monitoring to happen in real time, making the system more proactive rather than reactive (16,18,19,20).

The fast global rollout of COVID-19 vaccines and new treatments such as biologics, gene therapies, and cell therapies has further shown the importance of having strong, well-coordinated pharmacovigilance systems across countries to ensure medicine safety worldwide (16,18,22).

Needs of Pharmacovigilance

- **Post marketing safety surveillance:** Clinical trials are normally conducted in small, carefully selected groups of patients and for a limited period of time. Because of this they may fail to detect rare , delayed or population specific adverse drug reactions. Therefore, Post Marketing PV is essential to understand a medicine safety profile. PV ensures continuous monitoring of a drug through its entire life cycle from regulatory approval to widespread use in real-world clinical practice (16,23).

- **Protecting community health and maintaining benefits and risks:** PV systematically identifies, evaluates and helps to prevent adverse drug reaction and other medicine related problems to ensure that the benefits of medicines continue to outweigh their risks overtime (23,24,25). A strong PV system support the confidence of both healthcare professionals and patients and become an essential component of modern healthcare system and public health programs(24,25).

- **Assisting regulatory authorities in benefits -risk assessment and management**: Regulatory agencies such as the FDA, EMA, WHO, and national authorities rely on pharmacovigilance data to make important safety decisions, including updating product labels, issuing safety warnings, implementing risk management plans, and, when necessary, restricting or withdrawing medicines from the market (16,23,26). Pharmacovigilance systems and related legislation clearly define the responsibilities of both manufacturers and regulators and have become an essential part of regulatory frameworks worldwide (23,26).

- **Establishing international practices and standards:** Internationally coordinated pharmacovigilance systems are necessary due to the increased cross-border movement of medications and the complexity of global supply chains. Countries may exchange safety data pool information, and more efficiently identify safety signals thanks to initiatives like the WHO International Drug Monitoring Programme, VigiBase, and ICH-aligned standards (23,27). This international cooperation is particularly crucial for low- and middle-income nations, where pharmacovigilance systems must be strengthened to guarantee the safe and efficient use of both necessary and novel medications (27).

- **Incorporate safety monitoring into clinical work:** Pharmacovigilance connects clinical trials, day to day medicine use, and clinical decision-making by :

- Monitoring drug safety throughout all phases of clinical development and during routine healthcare practice (16,23).
- It helps guide safer prescribing by providing information on appropriate dosing, contraindications, and use in special populations (16,23).
- The active involvement of healthcare professionals and patients in reporting adverse drug reactions, thereby strengthening overall medicine safety (23,24).

- **Enhancing data reliability and completeness:** Pharmacovigilance continues to face significant obstacles, including underreporting of adverse medication reactions, low-quality data, low patient and healthcare professional knowledge, and disjointed reporting systems. These problems underscore the need for ongoing capacity building, improved training and education,

and a more robust reporting and safety culture (24,28).

Amendments in Pharmacovigilance

European Union

One of the most significant changes in recent global pharmacovigilance regulations has occurred in the EU:

- **Upgradation of the Pharmacovigilance System Master File (PSMF):** Documentation is now required only for significant or important deviations from pharmacovigilance protocols. intends to reduce the administrative load associated with PSUR-related documentation (29).

- **Signal detection and monitoring changes:** The EMA and national authorities take over continuous monitoring of EudraVigilance expanding the scope of data to include suspected adverse events starting in February 2026. Signal management procedures must be in line with Good Pharmacovigilance Practices (GVP) for MAHs (29).

- **Expanded Audit & Inspection Framework:** More generally, audits will include subcontra ctor supervision and cover all PV operations for a specified time frame (29).

- **Post-Authorisation Safety Studies (PASS) & PSURs:** New specifications for PSUR details that inc orporate risk-minimization efficacy and PASS protocol reg istration with the EMA (30).

- **Updated Reporting Terminology & Standards:** mandates the use of terms that have been esta blished globally (e.g., MedDRA, IDMP) (30).

United States

- **FDAAA(2007):** Despite being passed earlier, the FDAAA of 2007 greatly improved the FDA's postmarket safety powers by requiring safety studies, increasing risk communication and fortifying postmarketing surveillance. These modifications continue to be fundamental to American pharmacovigilance legislation (31).

- **FDA Publishes Adverse Event Data in Real Time:** The FDA, the U.S. Food and Drug Administration, started publishing adverse event data from its main safety database, FAERS (FDA Adverse Event Reporting System), every day in August 2025. Real-time reporting will now replace months long delays, increasing transparency and accelerating the discovery of safety signals. It is indicative of a shift toward more advanced safety monitoring equipment (31).

- **Electronic Submission of Safety Reports (ICH E2B(R3) Standards):** The FDA began accepting electronic submissions of premarketing and postmarketing safety reports (ICSRs) in the standardized ICH E2B(R3) format on January 16, 2024. The deadline for submitters to completely switch from earlier formats is April 1, 2026. This enhances data quality and interchange while bringing U.S. safety reporting into compliance with international standards (32).

- **Modernization of Postmarket Safety Reporting:** According to FDA requirements serious and unexpected adverse drug events must justify "alert reports" within 15 days. Manufacturers, licensees, or applicants are

required to report both domestic and globally serious adverse events within 15 working days of receipt. It is necessary to examine and assess every report as part of documented safety monitoring protocols (31).

Pharmacovigilance Program of India (PVPI)

The Pharmacovigilance Programme of India (PvPI) was officially introduced by the Government of India on July 14, 2010, to improve the drug safety surveillance through the nation. In order to facilitate systematic ADR reporting, 22 Adverse Drug Reaction Monitoring Centers (AMCs), including AIIMS New Delhi, were established as part of its initial deployment. To ensure the safe use of medications PVPI collects , analyzes and evaluates reports of adverse drug reaction through the national network of AMCs. In order to improve effective ADR reporting and monitoring procedures the program also places a strong focus on educating and inspiring healthcare providers (33).

Purpose of Pharmacovigilance Programme of India (PVPI)

- To protect the public's health by ensuring the benefits of medicines consistently justify their potential risks.
- To enhance healthcare professionals understanding of the significance of correct and timely ADR reporting .
- To evaluate and analyze adverse drug reactions within the Indian population.
- To constantly evaluate the benefit- risk profile of medicinal.
- To produce neutral, evidence based recommendations on drug safety.
- To support Central Drugs Standard Control Organization (CDSCO) in making informed regulatory decisions related to medication safety (34).

Structure and function of Pharmacovigilance Programme of India

- Patients, medical experts and the pharmaceutical industry all provide important safety information from different specific points. Therefore involving them assurance through participation in medication safety monitoring.
- Marketing license holders are required to provide Periodic Safety Update Reports (PSURs) which facilitate ongoing post marketing surveillance and aid in the identification of uncommon or long – term side effects that might not indicate during clinical trials.
- CDSCO's carefully examination of PSUR's ensure neutral regulatory supervision and rapid detection of possible safety issues.
- Adverse Drug Reaction Monitoring Centers (AMC's) facilities the reporting of Adverse Drug Reactions (ADRs) which encourages systematic, uniform and easily accessible data gathering globally.
- AMCs and the National Coordination Center (NCC) can communicate more effectively, accurately and in the moment when reports are transmitted electronically using VigiFlow.
- NCC-PVPI's centralized analysis ensure consistent review, enhanced data quality and professional scientific examination of all safety signals that are presented.
- By exchanging verified data with the Uppsala Monitoring Centers (UMC). India becomes a part of the global pharmacovigilance network, facilitating cross-border cooperation and early identification of global safety concerns.
- Public health is protected by communicating reviewed finding to CDSCO, which supports evidence based regulatory choices such label modifications, warnings, limitations or the removal of dangerous medications (34).

Another Milestone of Pharmacovigilance of India

International Collaboration

- **The World Health Organization (WHO):** International collaboration to improve pharmacovigilance and drug safety is the cornerstone of the WHO Programme for International Drug Monitoring. Adverse drug reactions are recorded in over 150 member countries, evaluated nationally at the Uppsala Monitoring Centre (UMC), and then processed and added to the worldwide VigiBase database. This shared system allows nations to analyze safety data, find similar patterns of negative reactions worldwide, and detect possible safety warnings early. The results of the study are shared with member nations to enable timely regulatory actions and protect public health (35,36).

- **International Council for Harmonisation (ICH):** The ICH is a global organization that brings together pharmaceutical businesses and regulatory agencies from the US, Japan, and the EU to develop consistent standards for the quality, safety, and efficacy of medications. In several countries, it was established in 1990 with the intention of simplifying regulatory processes and accelerating pharmaceutical development and clearance. Representatives from significant business groupings and regulatory bodies make up the ICH Steering Committee, which monitors these harmonization efforts. Organizations such as Health Canada and WHO participate as observers. It is through this collaborative framework that ICH promotes global drug regulation and pushes consistent international standards (37).

- **Council for International Organizations of Medical Science (CIOMS):** Working under the WHO framework, CIOMS is a global policy-based organization that provides expert guidance on pharmacovigilance practices and drugs safety. By generating reference papers and evidence-based recommendations through specialized working groups, it aids in the development of international regulatory policy. It offers guidelines for managing clinical trial safety data, improves signal detection and risk management processes, and establishes Development Safety Update Reports. CIOMS generally makes an important contribution to the worldwide pharmacovigilance standardization and strengthening (38).

- **International Society of Pharmacovigilance (ISOP):** The goal of the scientific non-profit International Society of Pharmacovigilance (ISOP) is to advance pharmacovigilance via research, education, and professional collaboration. It promotes scientific research, training, and knowledge sharing to promote the responsible and safe use of medicines around the world. The European Society of Pharmacovigilance was founded in 1992, and it has since expanded to become a worldwide organization of pharmacovigilance experts (38).

FUTURE DIRECTION

Pharmacovigilance is becoming a more globally coordinated field that depends on solid multinational collaborations to improve the safety of medicines. Early detection of uncommon and developing risks depends on enhancing global collaboration through coordinated capacity-building programs, harmonized regulatory requirements, and shared safety databases. In vaccine safety surveillance, for example,

multinational data-sharing platforms show how combining real-world data enhances signal detection and speeds up regulatory action. Clear legal and ethical frameworks for information exchange, accessible data platforms, and sustainable governance that actively involves industry, patients healthcare professionals, and regulators are all necessary for effective international cooperation. Focusing on accessibility and stakeholder participation will strengthen the adaptability of global pharmacovigilance networks (39,40).

Integration of pharmacovigilance across the entire product lifecycle—from clinical development to post-marketing surveillance—is becoming a critical strategy. Embedding safety endpoints within clinical trials, enabling real-time data monitoring, adopting adaptive trial designs, and implementing structured post-authorization safety studies support continuous safety evaluation. The use of linked electronic health records, claims databases, and registries enables broader population-level risk assessment and strengthens causal inference. This lifecycle approach promotes earlier risk identification, informed regulatory decisions, and proactive risk management planning (41,42).

Additionally, by facilitating real-time, patient-centered data collection, electronic health records are changing pharmacovigilance procedures. Modern analytics, wearable devices, online medical care, and mobile health apps offer continuous tracking of patient-reported outcomes, medication adherence, and physiological indicators that traditional methods could detect. These technologies enable automated signal recognition and prioritization when paired with artificial intelligence and natural language processing, increasing the speed and precision of safety evaluations. To ensure stability and ethical use, their effective implementation needs strong legal frameworks, consistent validation procedures, data privacy protections, accessibility, and equal access (43,44,45).

A cooperative, lifecycle-based, and electronically connected future pharmacovigilance ecosystem is highlighted by these developments taken together, which will ultimately improve global drug safety monitoring and safeguard public health (27,46,47).

CONCLUSION

Pharmacovigilance is evolving from the easily identification of drug-related risks to a systematic scientific and regulatory framework that is vital to public health protection. Besides pre-approval testing, historical events most notably the thalidomide tragedy showed the necessity of continuous post-marketing surveillance. Today, systematic reporting, risk management and benefit-risk evaluation have improved drug safety monitoring because to concerted international and national efforts encouraged by agencies like the WHO and initiatives like PvPI. Pharmacovigilance has become even more proactive and effective with the incorporation of digital technologies and real-world data. But issues like low awareness and underreporting still exist. To ensure safe medicines and enhance therapeutic results globally, it will be essential to enhance cooperation, education, and lifecycle safety monitoring.

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